



JAN 18 2013

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: December 11, 2012

Submitter: GE Medical Systems, LLC (doing business as GE Healthcare)
3200 N. Grandview Blvd
Waukesha, WI 53188
FDA Registration Number: 2183553

Primary Contact Person: Michelle Huettner
Regulatory Affairs Leader, MR
GE Medical Systems, LLC (doing business as GE Healthcare)
Phone (262) 521-6102
Fax (262) 546-0902

Secondary Contact Person: Glen Sabin
Regulatory Affairs Director, MR
GE Medical Systems, LLC (doing business as GE Healthcare)
Phone (262) 521-6848
Fax (262) 364-2785

Device: Trade Name: CardiacVX

Common/Usual Name: System, image processing, radiological- Picture archiving and communications system.

Classification Names: 21CFR 892.2050

Product Code: LLZ

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Predicate Device(s): GE Delta Software Option for MRI (marketed as ReportCARD) (K031927) manufactured by GE
READY View (K110573) manufactured by GE

Device Description: CardiacVX is a post-processing analytical software application, which provides tools for the review and reporting of cardiac MR datasets. Measurement tools on the report interface include: point, distance, area, and volume measurements (including ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements). Semi-automatic tools are available for left ventricular contour detection, valve plane detection, vessel contour detection for flow analysis, signal intensity analysis for myocardium and infarct sizing measurement, T2 Star analysis, and patent foramen ovale (PFO) analysis.

Indications for Use: The GE CardiacVX for MRI is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. CardiacVX can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows the access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in a cine mode to facilitate visualization.

A report input interface is also available. Measurement tools on the report interface make it possible to quickly and reliably fill out a complete clinical report of an imaging exam. Available tools include: point, distance, area, and volume measurement tools such as ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements.

Semi-automatic tools are available for left ventricular contour detection, valve plane detection, vessel contour detection for flow analysis, signal intensity analysis for myocardium and infarct sizing measurement, and T2 Star analysis.

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The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians.

When interpreted by a trained physician these tools may be useful in supporting the determination of a diagnosis.

Technology: The proposed medical device, CardiacVX, employs the same fundamental scientific technology as its predicate devices. The proposed device (CardiacVX) is substantially equivalent to the predicate devices because it is a post-processing software option for use on cardiac MR image datasets.

**Determination of
Substantial Equivalence:**

Summary of Non-Clinical Tests:

CardiacVX complies with voluntary standards, including the following process standards: ISO 13485, ISO 14971, and IEC 62304. Because CardiacVX is a software-only application which runs on the Advantage Workstation (AW), there are no applicable mandatory performance standards.

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The MR acquired clinical images that were used for the completion of verification and validation testing for CardiacVX was obtained from the GE Healthcare facilities under the provisions of a non-significant risk investigation for internal volunteer scanning. In addition,



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multi-vendor anonymized MR contrast-enhanced images were obtained from a third-party clinical research study.

Conclusion: GE Healthcare considers the CardiacVX application to be as safe, as effective, and performance is substantially equivalent to its predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 18, 2013

GE Medical Systems, LLC
% Michelle Huettner
3200 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K121762

Trade/Device Name: CardiacVX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 11, 2012
Received: December 12, 2012

Dear Ms. Huettner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121762

Device Name: Cardiac VX

Indications for Use:

The GE CardiacVX for MRI is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. CardiacVX can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows the access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in a cine mode to facilitate visualization.

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The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians.

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Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)

Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

510(k) K121762